APR 1 5 2009

1C083910

Section E: 510K Summary

Submitter
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Contact Person
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Date Prepared
28 November 2008

Software Information

Trade Name: VidiStar PACS & DICOM Viewer Software

Common Name:
- Picture Archiving and Communications Software System
- Digital Imaging and Communications in Medicine (DICOM) Viewer

Classification Name:
- System, Image Processing, Radiological
- Computer, Diagnostic, Programmable
- System, Digital Image Communications, Radiological

Device Description
The VidiStar PACS & DICOM Viewer Software System is a picture archiving and communications system software used to process, display, transfer, enable reports, communicate, store and archive digital medical images using Transmission Control Protocol/Internet Protocol (TCP/IP). It supports DICOM structured reports for creating, rendering, storage and archiving.

Indications For Use:
The VidiStar PACS & DICOM Viewer Software system is a picture archiving and communications system (PACS) intended to be used as a networked Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The VidiStar PACS & DICOM Viewer Software is comprised of modular software programs that run on standard "off-the-shelf" personal computers,

business computers, and servers running standard operating systems. VidiStar PACS & DICOM Viewer Software system is an image, data storage and display software that accepts DICOM data from laboratories, which support DICOM standard imaging data and structured reporting transfer(s). The system provides the capability to: organize images generated by OEM vendor equipment, perform digital manipulation, create graphical representations of anatomical areas, perform quantitative measurements, and create DICOM structure reports, all over the Internet.

All quantitative data ranges are derived from the clinical experience of laboratories and are included in observation libraries for VidiStar users. VidiStar strongly recommends that users review these ranges with their individual diagnostic needs in mind prior to using the VidiStar PACS & DICOM Viewer Software system for clinical reporting. The VidiStar PACS & DICOM Viewer Software system should not be used for reviewing full-field digital mammograms.

General Safety and Effectiveness Concerns
The device labeling and manual provide operating instructions for the safe and effective use of VidiStar PACS & DICOM Viewer Software. The display, storage, retrieval, and analysis of information provide a minor level of hazard concern.

Standard:
The VidiStar PACS & DICOM Viewer Software system is designed in accordance with product safety and performance requirements set forth in the following standard:

1. Digital Imaging and Communications in Medicine (DICOM)

Summary of Design Control Activities:
The design control activities used by VidiStar for software design and testing included the following quality assurance design control measures applied to the development of the VidiStar PACS & DICOM Viewer Software product:

7. Validation Planning
8. Testing Phase
9. ALPHA Testing
10. BETA Testing
11. Software Enhancements
12. Software Release Version Number

Substantial Equivalence
VidiStar PACS & DICOM Viewer Software is substantially equivalent to the 510(k) PACS products that are currently on the market. While there are some feature differences between the VidiStar device and the equivalent devices, these differences do not affect the safety or effectiveness of the new device. The VidiStar PACS & DICOM Viewer Software product includes additional medical disciplines which utilize DICOM and non-DICOM medical imaging standards. The VidiStar PACS & DICOM Viewer Software image viewer is a generic DICOM viewer that can operate over the Internet. This flexibility contributes to the effectiveness of the device, without compromising the safety. The VidiStar PACS &

DICOM Viewer Software is substantially equivalent to the following picture archiving and communications devices:

Feature	Heartlab, Inc Ascentia (formally Encompass)	Agfa Corp. Impax	Philips Inturis Suite	VidiStar PACS & DICOM Viewer Software
Operating System	Windows NT/2000/2003/XP	Windows NT	Windows NT	Linux and Windows 2000/XP
Image Source	DICOM	DICOM	DICOM	DICOM
Display Rates	Over 30 fps	Over 30 fps	Over 30 fps	Over 30 fps
Multiple Windows	Yes	Yes	Yes	Yes
Image Export	bmp, jpg, mpg	bmp,jpg,mpg	bmp,jpg,avi	bmp, jpg, png, avi
Network Access	Yes	Yes	Yes	Yes
Analysis	Yes	Yes	Yes	Yes
Reporting	Yes	Yes	Yes	Yes

Conclusions

With VidiStar PACS & DICOM Viewer Software digital medical images, from virtually any DICOM and non-DICOM digital imaging modality available today, can be processed, reviewed, measured, analyzed, reported, stored, and archived onto a server. The software can read DICOM images and most non-DICOM images, and allows for remote access to the PACS server's data via the Internet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2009

Mr. Craig A. Walker, MHA
Partner
VidiStar, LLC
P.O. Box 8539
GREENVILLE SC 29604-8539

Re: K083910
Trade/Device Name: VidiStar® PACS & DICOM Viewer Server Software System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 9, 2009
Received: March 11, 2009

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

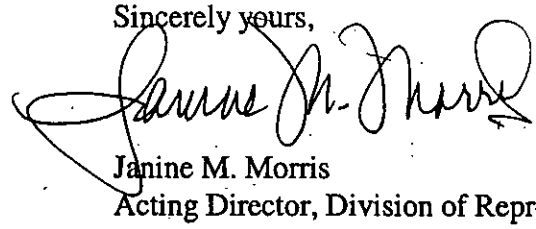
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D: Indications For Use

Applicant: VidiStar, LLC

510(k) Number (if known): K083910

Device Name: VidiStar® PACS & DICOM Viewer Server Software System

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(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083910

Prescription Use X Or Over-the-counter Use___
(Per 21 CFR 801.109)